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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,444	11/27/2001	Elizabeth Esther Mary Bates	DX0669KB	1324

24265 7590 02/26/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/994,444

Applicant(s)
Bates et al.

Examiner
G.R. Ewoldt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6 drawn to an A05F12 protein, fusion protein, and kit, classified in Class 435, subclass 810, and Class 530, subclass 350.

II. Claims 1-6 drawn to an A07C03 protein, fusion protein, and kit, classified in Class 435, subclass 810, and Class 530, subclass 386.

III. Claims 1-6 drawn to an E02B02 protein, fusion protein, and kit, classified in Class 435, subclass 810, and Class 530, subclass 380.

IV. Claims 7-10, drawn to a binding compound that specifically binds the A07C03 protein and a kit, classified in Class 530, subclass 387.1, and Class 435, subclass 810.

V. Claims 7-10, drawn to a binding compound that specifically binds the A05F12 protein and a kit, classified in Class 530, subclass 388.22, and Class 435, subclass 810.

VI. Claims 7-10, drawn to a binding compound that specifically binds the E02B02 protein and a kit, classified in Class 530, subclass 387.1, and Class 435, subclass 810.

VII. Claims 11-18, drawn to a polynucleotide encoding A05F12, a cell, and a kit, classified in Class 435, subclasses 252.3, 320.1, and 810 and Class 536, subclass 23.1.

VIII. Claims 11-18, drawn to a polynucleotide encoding A07C03, a cell, and a kit, classified in Class 435, subclasses 252.3, 320.1, and 810 and Class 536, subclass 23.53.

IX. Claims 11-18, drawn to a polynucleotide encoding E02B02, a cell, and a kit, classified in Class 435, subclasses 252.3, 320.1, and 810 and Class 536, subclass 23.5.

X. Claim 19, drawn to method of modulating physiology or development with a binding protein, classified in Class 435, subclass 375.

XI. Claim 19, drawn to method of modulating physiology or development with an anti-sense nucleic acid, classified in Class 435, subclass 375.

2. Inventions I-IX are different products. They are distinct because their structures and/or modes of action are different. The proteins of Inventions I-III are related to the polynucleotides of Inventions VII-IX by virtue of being encoded by same, and related to the binding proteins of Inventions IV-VI by being bound by same. However, nucleic acids and polypeptides are physically and functionally distinct chemical entities, as are polypeptides and the binding proteins which bind them. As the proteins of I-III are unrelated, the antibodies of IV-VI and the polynucleotides of VIII-IX are also unrelated. Therefore, the inventions are patentably distinct.

3. Inventions IV-VI and X are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in materially different processes, such as for *in vitro* assays.

4. The methods of Inventions X and XI are unrelated as they employ unrelated reagents acting through unrelated mechanisms.

5. This application contains inventions drawn to patentably distinct species. Should Applicant elect any of Inventions I-X Applicant is required under 35 U.S.C. § 121 to elect:

A) a **specific** sequence, such as SEQ ID NO:2, 4, 6, 8, 10, or 12,

B) and list all Claims readable thereon including those subsequently added. Currently all Claims are generic.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different proteins comprise unrelated biochemicals with unrelated functions. Therefore, the species are independent and patentable over one another.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and differing subclasses, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
February 24, 2002